510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k121231

B. Purpose for Submission:

Addition of the over-the-counter claim to a previously cleared device (k060810)

C. Measurand:

Amphetamine, Cocaine, Methamphetamine, Morphine and Cannabinoids

D. Type of Test:

Qualitative immunoassay

E. Applicant:

IND Diagnostic Inc.

F. Proprietary and Established Names:

IND Drug Home Multi-Panel Test (2-5) – Cassette and Strip Formats
IND Amphetamine Home Test – Cassette and Strip Formats
IND Methamphetamine Home Test – Cassette and Strip Formats
IND Cocaine Home Test – Cassette and Strip Formats
IND Morphine Home Test – Cassette and Strip Formats
IND Marijuana Home Test – Cassette and Strip Formats

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NFT	II	862.3100 – Amphetamine test system	91- Toxicology
NFY	II	862.3250 – Cocaine and Cocaine metabolites test system	91– Toxicology
NGG	II	862.3610 – Methamphetamine test system	91– Toxicology
NGI	II	862.3640 – Opiate test system	91– Toxicology
NFW	II	862.3870 – Cannabinoid test system	91– Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   IND Drug Home Multi-Panel Test (2-5) – Cassette and Strip Formats
   IND Amphetamine Home Test – Cassette and Strip Formats
   IND Methamphetamine Home Test – Cassette and Strip Formats
   IND Cocaine Home Test – Cassette and Strip Formats
   IND Morphine Home Test – Cassette and Strip Formats
   IND Marijuana Home Test – Cassette and Strip Formats

   The IND Drug Home Test is a rapid chromatographic immunoassay multi-panel or single drug test for the qualitative detection of one or more of the following drugs: Amphetamine, Methamphetamine, Cocaine, Marijuana and Morphine in human urine. It is intended for over-the-counter use.

Drug Name (code)	Cut-off
Amphetamine (AMP)	1000 ng/mL
Methamphetamine (MET)	1000 ng/mL
Cocaine (COC)	300 ng/mL
Marijuana (THC)	50 ng/mL
Morphine (MOR)	300 ng/mL

   The test is intended for over-the-counter (OTC) use as the first step in a two step process to provide consumers, with information concerning the presence or absence of the above stated drugs or metabolites in a urine sample. The test provides only preliminary test results. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS (Gas Chromatography/Mass Spectrometry) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive.

3. Special conditions for use statement(s):

   For over-the-counter (OTC) use

4. Special instrument requirements:

   Not applicable, as the devices are visually-read single-use devices.

I. Device Description:

The product may be sold as a single test or as part of a panel, and may be packaged in either a strip or a cassette format. Operators dip the test strip into the urine, or add drops of urine to the cassette test well to initiate the test reaction. Results are visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   One Step Drugs of Abuse Multi-Panel Test (2-5)
   One Step Morphine Test – Cassette and Strip Formats
   One Step Cocaine Test - Cassette and Strip Formats
   One Step Methamphetamine Test - Cassette and Strip Formats
   One Step Amphetamine Test - Cassette and Strip Formats
   One Step Marijuana - Cassette and Strip Formats

2. Predicate K number(s):

   k060810

3. Comparison with predicate:

Item	Device	Predicate
Indication for use	Qualitative detection of drugs-of-abuse in urine	Same
Intended Users	Over the Counter (OTC) Use	Prescription Use Only
Specimen	Urine	Same
Cutoff	Cocaine 300 ng/mL Methamphetamine 1000 ng/mL Amphetamine 1000 ng/mL Morphine 300 ng/mL Marijuana 50 ng/mL	Same
Read time	5 minutes	10-20 minutes
Storage	35.6 - 89 ^{o}F	Same
Results	Qualitative	Same
Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Strip, cassette and multi-panel	Same

K. Standard/Guidance Document Referenced (if applicable):

None were referenced

L. Test Principle:

The test is based on the principle of a competitive inhibition immunoassay, in which a chemically labeled drug (drug conjugate) competes with the drug which may be present in urine, for limited antibody binding sites. The test device consists of a membrane strip, which is pre-coated with DOA-BSA conjugate on the test band region, and a colored anti-DOA monoclonal antibody-colloid gold conjugate pad, which is placed at the end of the membrane. In the absence of drug in the urine, the colored antibody-colloid gold conjugate moves with the sample by capillary action along the membrane until it reaches the immobilized drug conjugate in the test band region. At this point, the antibody-colloid gold conjugate reacts with the pre-coated drug conjugate and forms a visible pink colored line as the antibodies form complexes with the drug conjugate. Therefore, formation of a visible pink color line on the test band region is interpreted as a negative test result. When the drug is present in the urine, the drug/metabolite antigen will compete with the drug conjugate coated in the test band region for the limited antibody sites. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites, and will prevent attachment of the colored antibody-colloid gold conjugate to drug conjugates pre-coated in the test band region. Therefore, absence of the pink color band on the test region indicates a positive result for the specified drug. A control line indicates that an adequate volume of sample was added and that the test membrane is intact.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   See performance data from k060810.

   b. Linearity/assay reportable range:

   Not applicable, the device is intended for qualitative use.

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   See performance data from k060810.

   d. Detection limit:

   See performance data from k060810.

e. Analytical specificity:

See performance data from k060810.

f. Assay cut-off:

See performance data from k060810.

2. Comparison studies:

a. Method comparison with predicate device:
A lay user study was performed with 100 lay users from three locations: Participants in the study were 43 females and 57 males tested all four devices. They had diverse educational and professional backgrounds and ranged in age from 19 to >60. 270 unaltered urine samples were used with the following concentration; negative, <50% of the cutoff. -50% to the cutoff, cutoff to 50% and >50% of the cutoff. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, for each device 16 blind labeled samples (4 sets of four for each device) and 4 device. The results are summarized below.

Single Test Strip Format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
THC	Positive	0	0	2	18	19	97.4
	Negative	328	10	22	1	0	99.4
AMP	Positive	0	0	3	20	21	97.6
	Negative	334	8	13	0	0	99.2
MET	Positive	0	0	2	14	16	96.7
	Negative	339	8	20	1	0	99.5
COC	Positive	0	0	3	19	23	97.7
	Negative	323	9	22	0	0	99.2
MOR	Positive	0	0	2	16	19	100
	Negative	334	10	19	0	0	99.5

Discordant table:

Strip Format

Sample Number	Viewer result	GC/MS result
THC-125-13	Negative	52
THC-75-5	Positive	41

Sample Number	Viewer result	GC/MS result
THC-75-2	Positive	48
AMP-75-10	Positive	981
AMP-75-6	Positive	995
AMP-75-11	Positive	912
MET-75-8	Positive	991
MET-75-6	Positive	941
MET-125-3	Negative	1030
COC-75-12	Positive	296
COC-75-6	Positive	297
COC-75-13	Positive	282
MOR-125-8	Positive	286
MOR-75-11	Positive	291

Single Test Cassette Format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
THC	Positive	0	0	2	20	19	100
	Negative	329	9	21	0	0	99.4
AMP	Positive	0	0	1	22	25	97.9
	Negative	328	5	18	1	0	99.7
MET	Positive	0	0	2	24	17	97.6
	Negative	325	5	26	1	0	99.4
COC	Positive	0	0	1	23	15	100
	Negative	345	3	13	0	0	99.7
MOR	Positive	0	0	1	29	17	95.8
	Negative	329	4	18	2	0	99.7

Discordant table:

Cassette Format

Sample Number	Viewer result	GC/MS result
THC-75-10	Positive	46
THC-75-9	Positive	49
AMP-75-8	Positive	980
AMP-125-5	Negative	1012
MET-75-3	Positive	943
MET-125-5	Negative	1120
MET-75-10	Positive	934

COC-75-13	Positive	297
MOR-125-8	Negative	329
MOR-125-5	Negative	314
MOR-75-8	Positive	278

Multi-Panel Strip Format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
THC	Positive	0	0	0	22	14	100
	Negative	332	18	14	0	0	100
AMP	Positive	0	0	1	14	19	97.1
	Negative	335	11	18	2	0	99.7
MET	Positive	0	0	2	18	21	100
	Negative	331	8	20	0	0	99.4
COC	Positive	0	0	1	16	14	96.8
	Negative	340	4	23	1	0	99.7
MOR	Positive	0	0	1	28	13	97.6
	Negative	328	5	24	1	0	99.7

Discordant table:

Multi-Strip Format

Sample Number	Viewer result	GC/MS result
AMP-125-1	Negative	1103
AMP-75-7	Positive	945
AMP-125-15	Negative	1119
MET-75-9	Positive	934
MET-75-14	Positive	944
COC-75-8	Positive	282
COC-125-4	Negative	329
MOR-75-13	Positive	258
MOR-125-10	Negative	313

Multi-Panel Cassette Format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
THC	Positive	0	0	1	27	13	100
	Negative	339	5	15	0	0	99.7
AMP	Positive	0	0	1	26	13	97.5
	Negative	338	6	15	1	0	99.7
MET	Positive	0	0	1	23	17	97.6
	Negative	338	3	17	1	0	99.7
COC	Positive	0	0	2	27	20	95.9
	Negative	321	8	20	2	0	99.7
MOR	Positive	0	0	1	19	20	100
	Negative	320	11	29	0	0	99.7

Discordant table:

Multi-Cassette Format

Sample Number	Viewer result	GC/MS result
THC-75-11	Positive	45
AMP-75-1	Positive	976
AMP-125-4	Negative	1024
MET-125-14	Negative	1106
MET-75-2	Positive	901
COC-125-7	Negative	314
COC-75-13	Positive	297
COC-125-2	Negative	321
COC-75-11	Positive	293
MOR-75-10	Positive	286

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix, urine

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.